REMARKS

Claims 1-3, 5, and 39-58 were previously pending, of which claims 51-58 were withdrawn from consideration as being drawn to a non-elected invention. By this amendment claims 1, 42, 45, and 48 are currently amended; claims 2, 3, 5, 39-41, 43, 44, 46, 47, 49, 50, and 51-58 are canceled without prejudice or disclaimer; and no new claims are added. No new matter has been added. Upon entry of this amendment claims 1, 42, 45, and 48 remain pending and under examination.

Claim 1 is currently amended to incorporate the limitations of canceled claims 5 and 39, as well as to word the claim substantially in accord with what the examiner acknowledged to be enabled (see page 3 of Office Action).

Rejections Under 35 U.S.C. § 112, First Paragraph

The examiner maintained the previous rejection of claims 1-3, 5, and 39-50 under 35 U.S.C. 112, first paragraph, for alleged lack of enablement. On page 3 of the Office Action the examiner acknowledged that the specification is enabling for a method of treating a subject for myocardial infarction, comprising the step of administering to the subject in need of such treatment a composition comprising a replication-defective adenovirus comprising a polynucleotide, wherein said composition is administered acutely into the apical and anterolateral free wall of the heart, wherein said polynucletotide comprises a nucleotide sequence that encodes an Akt polypeptide, operatively linked to a promoter to promote expression of the Akt polypeptide in cardiomyocytes, wherein the Akt polypeptide comprises the amino acid sequence of SEQ ID NO:2.

Without conceding to the merits of the examiner's position or the arguments made by the examiner in support thereof, and solely for the purpose of advancing prosecution, Applicant has amended claim 1 in accordance with the invention acknowledged by the examiner to be enabled. Claims 42, 45, and 48 are currently amended to substitute "polynucleotide" for "Akt nucleic acid" and to substitute "nucleotide sequence" for "nucleic acid sequence", in accord with

amended claim 1. Claims 2, 3, 5, 39-41, 43, 44, 46, 47, 49, 50, and 51-58 are canceled by this amendment. Accordingly, Applicant submits the claims are enabled as already acknowledged by the examiner, and Applicant respectfully requests the examiner to reconsider and withdraw the rejection of claims 1-3, 5, and 39-50 under 35 U.S.C. 112, first paragraph, for alleged lack of enablement.

For the record, Applicant notes that on page 3 of the Office Action the examiner indicated the species election requirement has been withdrawn. The species election was made among various specific nucleic acid (NA) sequences (SEQ ID NOs: 1, 3, and 5) and amino acid (AA) sequences (SEQ ID NOs: 2, 4, and 6). Claim 1 previously specified "the Akt nucleic acid comprises a nucleic acid sequence encoding an Akt polypeptide which shares at least 98% amino acid identity with SEQ ID NO:2." On page 11 of the Office Action the examiner made the following remarks, which suggest the acknowledged enablement should have extended to include all species recited above:

> Regarding Applicants contention that it is predictable that the Akt polypeptide encoded by the nucleic acid cited in the claims and human Akt would have the same biological function based on their high sequence homology, the Examiner acknowledges and concedes that in some instances homology between two polypeptides can predict biological function. However, the Examiner recognizes that while the ultimate factor having the therapeutic effect is the Akt polypeptide, the claims under consideration are drawn to administration of a nucleic acid, e.g., gene therapy, and not to the administration of the polypeptide. In the instant case, there are several reviews in the art which show that difficulties with vector selection, mode of delivery and persistence of predictable and effective levels of expression of the protein, have created technical barriers to the practice of gene therapy methods.

These remarks by the examiner suggest that the enablement rejection rests not so much on the use of highly homologous nucleic acid sequences as it does on other technical considerations. Applicant wishes to point out that the examiner appears to have acknowledged enablement for all the supposed technical barriers to the practice of gene therapy methods in connection with claim 1 as currently amended. This, together with the acknowledgement and concession by the examiner that homology between two polypeptides can predict biological

function, and the examiner's withdrawal of the species requirement, suggests Applicant should be entitled to a broader scope of protection in respect of the nucleic acid and amino acid sequences than is currently claimed. Applicant expressly reserves the right to pursue such broader scope of protection in, for example, one or more continuing applications.

Also for the record, Applicant notes that on pages 11-12 of the Office Action the examiner appears to continue to rely on optimization as a standard for enablement. Applicant respectfully submits optimization is not required to establish enablement.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the application in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By _____

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